

WHAT IS CLAIMED IS:

1. A sterilization indicator comprising a substrate and an indicator composition disposed thereon, wherein the indicator composition comprises:
  - 5 at least one salt of a transition metal;
  - at least one colorant that changes color when exposed to a sterilant; and
  - at least one binder resin.
2. The sterilization indicator of claim 1, wherein the transition metal is  
10 selected from the group consisting of Group VIB, Group VIII, and Group IB transition metals, and combinations thereof.
3. The sterilization indicator of claim 1, wherein the sterilant is hydrogen peroxide or peracetic acid.
- 15 4. The sterilization indicator of claim 1, wherein the colorant is selected from the group of classes of colorants consisting of Methane, Monoazo, Diazo, Triazo, Diazine, Thiazine, Xanthene, Oxazine, Cyanine, Anthraquinone, Benzodifuranone, Styryl, Phthalocyanine, Quinophthalone, Nitro, and Nitroso  
20 colorants, and combinations thereof, and/or the colorant is selected from the group consisting of Victoria green S extra, Basic blue 41, Basic red 15, Acid green AX986, Keystone soap fluoro green, Basic red 14, and combinations thereof.
- 25 5. The sterilization indicator of claim 1, wherein the indicator composition further comprises at least one colorant that does not change color when exposed to the sterilant.
6. A hydrogen peroxide indicator comprising a substrate and an indicator  
30 composition disposed thereon, wherein the indicator composition comprises:
  - at least one salt of a transition metal;

at least one colorant selected from the group of classes of colorants consisting of Methane, Monoazo, Diazo, Triazo, Diazine, Thiazine, Xanthene, Oxazine, and Anthraquinone colorants, and combinations thereof, and/or at least one colorant selected from the group consisting of Victoria green S extra, Basic blue 41, Basic red 15, Acid green AX986, Keystone soap fluoro green, Basic red 14, and combinations thereof; and

at least one binder resin.

7. The hydrogen peroxide indicator of claim 6, wherein the indicator composition further comprises at least one colorant that does not change color when exposed to hydrogen peroxide vapor.

8. The hydrogen peroxide indicator of claim 6, wherein the salt of a transition metal is selected from the group consisting of a copper salt, a cobalt salt, an iron salt, a chromium salt, and combinations thereof.

9. The hydrogen peroxide indicator of claim 8, wherein the indicator comprises at least one iron salt.

10. The hydrogen peroxide indicator of claim 9, wherein the colorant is selected from the group consisting of Patent blue violet, Alkali blue 4B, Victoria pure blue BO, Acid fuchsin sodium salt, Alphazurine A, Methyl violet 2B, Ethyl violet, FD/C blue 1, Brilliant blue R, Lissamine green B, Erioglaucine, Eriochrome black T, Eriochrome blue black B, Cibacron brilliant red 3B, Chromotrope 2B, Amaranth, D&C red No. 33, Bordeaux R, Acid violet 7, Acid violet 5, Plasmocorinth B, Acid blue 113, Acid red 151, Acid black 24, Acid red 97, Direct red 75, Brilliant crocein MOO, Ponceau SS, Reactive black 5, Arsenazo 111, Direct blue 71, Azocarmine G, Methylene violet 3RAX, Toluidine blue O, Methylene green, Sulforhodamine B, Rhodanine 6G, Violamine R, Nile blue A, Basic blue 3, Brilliant cresyl blue BB, Basic red 15, Alizarin violet 3R, Victoria green S extra, Basic blue 41, Acid green AX986,

Keystone soap fluoro green, Basic red 14, D&C green No. 5, and combinations thereof.

11. The hydrogen peroxide indicator of claim 10, wherein the colorant is  
5 selected from the group consisting of Victoria pure blue BO, Acid fuchsin  
sodium salt, Alphazurine A, Methyl violet 2B, Ethyl violet, FD/C blue 1,  
Brilliant blue R, Lissamine green B, Erioglaucine, Eriochrome black T,  
Eriochrome blue black B, Cibacron brilliant red 3B, Chromotrope 2B, D&C red  
No. 33, Acid violet 7, Acid violet 5, Plasmocorinth B, Acid blue 113, Acid red  
10 151, Acid black 24, Acid red 97, Direct red 75, Brilliant crocein MOO, Ponceau  
SS, Reactive black 5, Arsenazo 111, Azocarmine G, Methylene violet 3RAX,  
Toluidine blue O, Methylene green, Sulforhodamine B, Rhodanine 6G,  
Violamine R, Nile blue A, Basic blue 3, Brilliant cresyl blue BB, Basic red 15,  
Alizarin violet 3R, Victoria green S extra, Basic blue 41, Acid green AX986,  
15 Keystone soap fluoro green, Basic red 14, D&C green No. 5, and combinations  
thereof.

12. A hydrogen peroxide indicator comprising a substrate and an indicator  
composition disposed thereon, wherein the indicator composition comprises:  
20 at least one salt of cobalt, copper, chromium, and combinations thereof;  
at least one colorant that changes color when exposed to hydrogen  
peroxide vapor; and  
at least one binder resin.

13. The hydrogen peroxide indicator of claim 12, wherein the salt is selected  
25 from the group consisting of cobalt chloride, cobalt acetate, cupric chloride,  
cupric sulfate, cupric acetate, chromium potassium sulfate, and combinations  
thereof.

14. The hydrogen peroxide indicator of claim 12, wherein the colorant is  
30 selected from the group of classes of colorants consisting of Methane, Monoazo,

Diazo, Triazo, Diazine, Thiazine, Cyanine, Xanthene, Oxazine, and Anthraquinone colorants, and combinations thereof, and/or the colorant is selected from the group consisting of Victoria green S extra, Basic blue 41, Basic red 15, Acid green AX986, Keystone soap fluoro green, Basic red 14, and combinations thereof.

15. The hydrogen peroxide indicator of claim 12, wherein the indicator composition further comprises at least one colorant that does not change color when exposed to hydrogen peroxide vapor.

16. The hydrogen peroxide indicator of claim 12, wherein the indicator composition comprises at least one cobalt salt.

17. The hydrogen peroxide indicator of claim 16, wherein the colorant is selected from the group of classes of colorants consisting of Methane, Monoazo, Diazo, Oxazine, and Anthraquinone colorants, and combinations thereof.

18. The hydrogen peroxide indicator of claim 17, wherein the colorant is selected from the group consisting of Patent blue violet, Aniline blue, Erioglaucine, Arsenazo 1, Acid blue 92, Eriochrome blue black B, Congo red, Acid blue 29, Nile blue A, Reactive blue 2, Basic red 15, D&C green No. 5, and combinations thereof.

19. The hydrogen peroxide indicator of claim 12, wherein the indicator comprises at least one copper salt.

20. The hydrogen peroxide indicator of claim 19, wherein the colorant is selected from the group of classes of colorants consisting of Methane, Monoazo, Diazo, Triazo, Diazine, Thiazine, Xanthene, Oxazine, Cyanine, and Anthraquinone colorants, and combinations thereof, and/or the colorant is selected from the group consisting of Victoria green S extra, Basic blue 41,

Basic red 15, Acid green AX986, Keystone soap fluoro green, Basic red 14, and combinations thereof.

21. The hydrogen peroxide indicator of claim 20, wherein the colorant is  
5 selected from the group consisting of Alphazurine A, Methyl violet 2B, Ethyl  
violet, FD/C blue 1, Brilliant blue R, Lissamine green B, Erioglaucine, Victoria  
pure blue BO, Acid fuchsin sodium salt, Patent blue violet, Guinea green B,  
Coomassie violet R 150, Mordant brown 48, Chromotrope 2B, D&C red No. 33,  
Bordeaux R, Acid violet 7, Acid violet 5, Plasmocorinth, Acid red 151, Acid  
10 blue 29, Acid black 24, Acid red 97, Direct red 75, Brilliant crocein MOO,  
Ponceau SS, Reactive black 5, Arsenazo 111, Direct blue 71, Azocarmine G,  
Methylene violet 3RAX, Toluidine blue O, Azure B, Methylene green,  
Sulforhodamine B, Rhodanine 6G, Violamine R, Nile blue A, Basic blue 3,  
Brilliant cresyl blue BB, Quinaldine red, Basic red 15, Alizarin violet 3R,  
15 Reactive blue 2, Victoria green S extra, Basic blue 41, Acid green AX986,  
Keystone soap fluoro green, Basic red 14, D&C green No. 5, Fast green FCF,  
and combinations thereof.

22. The hydrogen peroxide indicator of claim 20, wherein the colorant is  
20 selected from the group of classes of colorants consisting of Methane, Monoazo,  
Diazo, Diazine, Thiazine, Xanthene, Oxazine, and Cyanine colorants, and  
combinations thereof, and/or the colorant is selected from the group consisting  
of Victoria green S extra, Basic blue 41, Basic red 15, Acid green AX986,  
Keystone soap fluoro green, Basic red 14, and combinations thereof.

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23. The hydrogen peroxide indicator of claim 22, wherein the colorant is  
selected from the group consisting of Alphazurine A, Methyl violet 2B, Ethyl  
violet, FD/C blue 1, Brilliant blue R, Lissamine green B, Erioglaucine, Victoria  
pure blue BO, Acid fuchsin sodium salt, Coomassie violet R 150, Mordant  
30 brown 48, Acid violet 5, Plasmocorinth, Acid red 151, Acid blue 29, Acid black  
24, Acid red 97, Direct red 75, Arsenazo 111, Azocarmine G, Methylene violet

3RAX, Toluidine blue O, Methylene green, Rhodanine 6G, Basic blue 3, Brilliant cresyl blue BB, Quinaldine red, Basic red 15, Reactive blue 2, Victoria green S extra, Basic blue 41, Keystone soap fluoro green, Basic red 14, D&C green No. 5, and combinations thereof.

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24. The hydrogen peroxide indicator of claim 12, wherein the indicator comprises at least one chromium salt.

25. The hydrogen peroxide indicator of claim 24, wherein the colorant is  
10 selected from the group of classes of colorants consisting of Methane, Monoazo, Diazo, and Cyanine colorants, and combinations thereof.

26. The hydrogen peroxide indicator of claim 25, wherein the colorant is  
15 selected from the group consisting of Ethyl violet, Eriochrome black T, Eriochrome blue black B, Congo red, Acid blue 113, Quinaldine red, and combinations thereof.

27. The hydrogen peroxide indicator of claim 26, wherein the colorant is  
20 selected from the group consisting of Ethyl violet, Eriochrome black T, Eriochrome blue black B, Acid blue 113, Quinaldine red, and combinations thereof.

28. A peracetic acid indicator comprising a substrate and an indicator  
composition disposed thereon, wherein the indicator composition comprises:  
25 at least one salt of a transition metal;  
at least one colorant selected from the group of classes of colorants  
consisting of Monoazo and Diazo colorants, and combinations thereof, and/or at  
least one colorant selected from the group consisting of Victoria green S extra,  
Basic blue 41, Basic red 15, Acid green AX986, Keystone soap fluoro green,  
30 Basic red 14, and combinations thereof; and  
at least one binder resin.

29. The peracetic acid indicator of claim 28, wherein the indicator composition further comprises at least one colorant that does not change color when exposed to peracetic acid.

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30. A peracetic acid indicator comprising a substrate and an indicator composition disposed thereon, wherein the indicator composition comprises:  
at least one salt of copper, cobalt, and combinations thereof;  
at least one colorant that changes color when exposed to peracetic acid;  
10 and  
at least one binder resin.

31. The peracetic acid indicator of claim 30, wherein the indicator composition further comprises at least one colorant that does not change color  
15 when exposed to peracetic acid.

32. The peracetic acid indicator of claim 30, wherein the indicator composition comprises at least one copper salt.

20 33. The peracetic acid indicator of claim 32, wherein the colorant is selected from the group of classes of colorants consisting of Monoazo and Diazo colorants, and combinations thereof, and/or the colorant is selected from the group consisting of Victoria green S extra, Basic blue 41, Basic red 15, Acid green AX986, Keystone soap fluoro green, Basic red 14, and combinations  
25 thereof.

34. The peracetic acid indicator of claim 33, wherein the colorant is selected from the group consisting of Acid violet 7, Evans blue, Naphthol blue black, Reactive black 5, Brilliant black BN, Azocarmine B, and combinations thereof.

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35. The peracetic acid indicator of claim 30, wherein the indicator composition comprises at least one cobalt salt.

36. The peracetic acid indicator of claim 35, wherein the colorant is selected from the group of classes of colorants consisting of Monoazo and Diazo colorants, and combinations thereof.

37. The peracetic acid indicator of claim 36, wherein the colorant is selected from the group consisting of Cibacron brilliant red 3B, Evans blue, Reactive black 5, Brilliant black BN, and combinations thereof.

38. A method of monitoring a sterilization process, the method comprising:  
providing an indicator comprising a substrate and an indicator composition comprising:  
at least one salt of a transition metal;  
at least one colorant that changes color when exposed to a sterilant; and  
at least one binder resin;  
providing an article to be sterilized; and  
exposing the indicator and the article to be sterilized to a sterilant.

39. A method of monitoring a hydrogen peroxide sterilization process, the method comprising:  
providing a hydrogen peroxide indicator comprising a substrate and an indicator composition comprising:  
at least one salt of a transition metal;  
at least one colorant selected from the group of classes of colorants consisting of Methane, Monoazo, Diazo, Triazo, Diazine, Thiazine, Cyanine, Xanthene, Oxazine, Anthraquinone, Benzodifuranone, Styryl, Phthalocyanine, Quinophthalone, Nitro, and Nitroso colorants, and combinations thereof, and/or at least one colorant selected from the

group consisting of Victoria green S extra, Basic blue 41, Basic red 15, Acid green AX986, Keystone soap fluoro green, Basic red 14, and combinations thereof; and

at least one binder resin;

5 providing an article to be sterilized; and

exposing the hydrogen peroxide indicator and the article to be sterilized to hydrogen peroxide vapor.

40. The method of claim 39, wherein the salt of a transition metal is selected from the group consisting of cupric chloride, ferrous chloride, cobalt chloride, cobalt acetate, cupric sulfate, ferrous sulfate, chromium potassium sulfate, cupric acetate, and combinations thereof.

41. The method of claim 39, wherein the indicator composition further comprises at least one colorant that does not change color when exposed to hydrogen peroxide vapor.

42. A method of monitoring a hydrogen peroxide sterilization process, the method comprising:

20 providing a hydrogen peroxide indicator comprising a substrate and an indicator composition comprising:

at least one salt of copper, chromium, iron, cobalt, and combinations thereof;

25 at least one colorant that changes color when exposed to hydrogen peroxide vapor; and

at least one binder resin;

providing an article to be sterilized; and

exposing the hydrogen peroxide indicator and the article to be sterilized to hydrogen peroxide vapor.

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43. The method of claim 42, wherein the colorant is selected from the group of classes of colorants consisting of Methane, Monoazo, Diazo, Triazo, Diazine, Thiazine, Cyanine, Xanthene, Oxazine, Anthraquinone colorants, and combinations thereof, and/or the colorant is selected from the group consisting of Victoria green S extra, Basic blue 41, Basic red 15, Acid green AX986, Keystone soap fluoro green, Basic red 14, and combinations thereof.

44. The method of claim 42, wherein the indicator composition comprises at least one cobalt salt.

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45. The method of claim 44, wherein the colorant is selected from the group of classes of colorants consisting of Methane, Monoazo, Diazo, Oxazine, and Anthraquinone colorants, and combinations thereof.

46. The method of claim 45, wherein the colorant is selected from the group consisting of Patent blue violet, Aniline blue, Erioglaucine, Arsenazo 1, Acid blue 92, Eriochrome blue black B, Congo red, Acid blue 29, Nile blue A, Reactive blue 2, Basic red 15, D&C green No. 5, and combinations thereof.

47. The method of claim 42, wherein the indicator composition comprises at least one copper salt.

48. The method of claim 47, wherein the colorant is selected from the group of classes of colorants consisting of Methane, Monoazo, Diazo, Triazo, Diazine, Thiazine, Xanthene, Oxazine, Cyanine, and Anthraquinone colorants, and combinations thereof, and/or the colorant is selected from the group consisting of Victoria green S extra, Basic blue 41, Basic red 15, Acid green AX986, Keystone soap fluoro green, Basic red 14, and combinations thereof.

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49. The method of claim 48, wherein the colorant is selected from the group consisting of Alphazurine A, Methyl violet 2B, Ethyl violet, FD/C blue 1, Brilliant blue R, Lissamine green B, Erioglaucine, Victoria pure blue BO, Acid fuchsin sodium salt, Patent blue violet, Guinea green B, Coomassie violet R 150, Mordant brown 48, Chromotrope 2B, D&C red No. 33, Bordeaux R, Acid violet 7, Acid violet 5, Plasmocorinth, Acid red 151, Acid blue 29, Acid black 24, Acid red 97, Direct red 75, Brilliant crocein MOO, Ponceau SS, Reactive black 5, Arsenazo 111, Direct blue 71, Azocarmine G, Methylene violet 3RAX, Toluidine blue O, Azure B, Methylene green, Sulforhodamine B, Rhodanine 6G, Violamine R, Nile blue A, Basic blue 3, Brilliant cresyl blue BB, Quinaldine red, Basic red 15, Alizarin violet 3R, Reactive blue 2, Victoria green S extra, Basic blue 41, Acid green AX986, Keystone soap fluoro green, Basic red 14, D&C green No. 5, Fast green FCF, and combinations thereof.
50. The method of claim 49, wherein the colorant is selected from the group consisting of Alphazurine A, Methyl violet 2B, Ethyl violet, FD/C blue 1, Brilliant blue R, Lissamine green B, Erioglaucine, Victoria pure blue BO, Acid fuchsin sodium salt, Coomassie violet R 150, Mordant brown 48, Acid violet 5, Plasmocorinth, Acid red 151, Acid blue 29, Acid black 24, Acid red 97, Direct red 75, Arsenazo 111, Azocarmine G, Methylene violet 3RAX, Toluidine blue O, Methylene green, Rhodanine 6G, Basic blue 3, Brilliant cresyl blue BB, Quinaldine red, Basic red 15, Reactive blue 2, Victoria green S extra, Basic blue 41, Keystone soap fluoro green, Basic red 14, D&C green No. 5, and combinations thereof.
51. The method of claim 42, wherein the indicator composition comprises at least one iron salt.
52. The method of claim 51, wherein the colorant is selected from the group of classes of colorants consisting of Methane, Monoazo, Diazo, Triazo, Diazine, Thiazine, Cyanine, Xanthene, Oxazine, and Anthraquinone colorants, and

combinations thereof, and/or the colorant is selected from the group consisting of Victoria green S extra, Basic blue 41, Basic red 15, Acid green AX986, Keystone soap fluoro green, Basic red 14, and combinations thereof.

- 5 53. The method of claim 52, wherein the colorant is selected from the group consisting of Patent blue violet, Alkali blue 4B, Victoria pure blue BO, Acid fuchsin sodium salt, Alphazurine A, Methyl violet 2B, Ethyl violet, FD/C blue 1, Brilliant blue R, Lissamine green B, Erioglaucine, Eriochrome black T, Eriochrome blue black B, Cibacron brilliant red 3B, Chromotrope 2B,
- 10 Amaranth, D&C red No. 33, Bordeaux R, Acid violet 7, Acid violet 5, Plasmocorinth B, Acid blue 113, Acid red 151, Acid black 24, Acid red 97, Direct red 75, Brilliant crocein MOO, Ponceau SS, Reactive black 5, Arsenazo 111, Direct blue 71, Azocarmine G, Methylene violet 3RAX, Toluidine blue O, Methylene green, Sulforhodamine B, Rhodanine 6G, Violamine R, Nile blue A,
- 15 Basic blue 3, Brilliant cresyl blue BB, Quinaldine red, Basic red 15, Alizarin violet 3R, Victoria green S extra, Basic blue 41, Acid green AX986, Keystone soap fluoro green, Basic red 14, D&C green No. 5, and combinations thereof.
54. The method of claim 53, wherein the colorant is selected from the group
- 20 consisting of Victoria pure blue BO, Acid fuchsin sodium salt, Alphazurine A, Methyl violet 2B, Ethyl violet, FD/C blue 1, Brilliant blue R, Lissamine green B, Erioglaucine, Eriochrome black T, Eriochrome blue black B, Cibacron brilliant red 3B, Chromotrope 2B, D&C red No. 33, Acid violet 7, Acid violet 5, Plasmocorinth B, Acid blue 113, Acid red 151, Acid black 24, Acid red 97,
- 25 Direct red 75, Brilliant crocein MOO, Ponceau SS, Reactive black 5, Arsenazo 111, Azocarmine G, Methylene violet 3RAX, Toluidine blue O, Methylene green, Sulforhodamine B, Rhodanine 6G, Violamine R, Nile blue A, Basic blue 3, Brilliant cresyl blue BB, Basic red 15, Alizarin violet 3R, Victoria green S extra, Basic blue 41, Acid green AX986, Keystone soap fluoro green, Basic red
- 30 14, D&C green No. 5, and combinations thereof.

55. The method of claim 42, wherein the indicator composition comprises a chromium salt.

56. The method of claim 55, wherein the colorant is selected from the group of classes of colorants consisting of Methane, Monoazo, Diazo, and Cyanine colorants, and combinations thereof.

57. The method of claim 56, wherein the colorant is selected from the group consisting of Ethyl violet, Eriochrome black T, Eriochrome blue black B, Congo red, Acid blue 113, Quinaldine red, and combinations thereof.

58. The method of claim 57 wherein the colorant is selected from the group consisting of Ethyl violet, Eriochrome black T, Eriochrome blue black B, Acid blue 113, Quinaldine red, and combinations thereof.

59. A method of monitoring a peracetic acid sterilization process, the method comprising:

providing a peracetic acid indicator comprising a substrate and an indicator composition comprising:

at least one salt of a transition metal;

at least one colorant selected from the group of classes of colorants consisting of Monoazo, Diazo, Benzodifuranone, Styryl, Phthalocyanine, Quinophthalone, Nitro, and Nitroso colorants, and combinations thereof, and/or at least one colorant selected from the group consisting of

Victoria green S extra, Basic blue 41, Basic red 15, Acid green AX986, Keystone soap fluoro green, Basic red 14, and combinations thereof; and

at least one binder resin;

providing an article to be sterilized; and

exposing the peracetic acid indicator and the article to be sterilized to liquid peracetic acid.

60. The method of claim 59 wherein the salt of a transition metal is selected from the group consisting of cupric acetate, cobalt acetate, cupric sulfate, and combinations thereof.

5 61. A method of monitoring a peracetic acid sterilization process, the method comprising:

providing a peracetic acid indicator comprising a substrate and an indicator composition comprising:

at least one salt of copper, cobalt, and combinations thereof;

10 at least one colorant that changes color when exposed to liquid peracetic acid; and

at least one binder resin;

providing an article to be sterilized; and

15 exposing the peracetic acid indicator and the article to be sterilized to liquid peracetic acid.

62. The method of claim 61, wherein the colorant is selected from the group of classes of colorants consisting of Monoazo and Diazo colorants, and combinations thereof, and/or the colorant is selected from the group consisting  
20 of Victoria green S extra, Basic blue 41, Basic red 15, Acid green AX986, Keystone soap fluoro green, Basic red 14, and combinations thereof.

63. The method of claim 61, wherein the indicator composition comprises at least one copper salt.  
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64. The method of claim 63, wherein the colorant is selected from the group of classes of colorants consisting of Monoazo and Diazo colorants, and combinations thereof, and/or the colorant is selected from the group consisting of Victoria green S extra, Basic blue 41, Basic red 15, Acid green AX986,  
30 Keystone soap fluoro green, Basic red 14, and combinations thereof.

65. The method of claim 64, wherein the colorant is selected from the group consisting of Acid violet 7, Evans blue, Naphthol blue black, Reactive black 5, Brilliant black BN, Azocarmine B, and combinations thereof.

5 66. The method of claim 61, wherein the indicator composition comprises at least one cobalt salt.

67. The method of claim 66, wherein the colorant is selected from the group of classes of colorants consisting of Monoazo and Diazo colorants, and  
10 combinations thereof.

68. The method of claim 67, wherein the colorant is selected from the group consisting of Cibacron brilliant red 3B, Evans blue, Reactive black 5, Brilliant black BN, and combinations thereof.